## R E M A R K S

Objection to Specification

The disclosure was objected to on page 2 of the Office Action for the reason that the term "antimicrobial" was not spelled correctly on page 6 of the specification. The specification was amended hereinabove to correct the spelling of "antimicrobial."

Withdrawal of the objection to the specification is respectfully requested.

Claim Amendments

Claims 1 to 4, 6, 7, 9 and 13 to 17 were canceled hereinabove.

Claim 8 was amended to include the features of claim 9.

Claim 8 was also amended to include a feature (drug concentration sustenability) which is supported in the paragraph bridging pages 12 and 13 of the specification.

Claim 12 was amended to include drugs that are disclosed on page 6, lines 15 to 16 of the specification (see the CORRECTED

ENGLISH-LANGUAGE TRANSLATION OF INTERNATIONAL APPLICATION OF PCT/JP03/01897 filed on June 26, 2007).

Claim Objections

Claims 1, 2, 7, 12 and 17 were objected to for informalities (see the last paragraph on page 2 of the Office Action). The informalities involved the incorrect spelling of the terms "subconjunctivally" in claim 1, "subconjunctival" in claim 2 and "antimicrobial" in claims 7, 12 and 17.

In view of the cancellation of claims 1 and 2, 7 and 17 hereinabove and the deletion of the terminology of "antimicrobial" in claim 12 hereinabove, withdrawal of the claim objections is respectfully solicited.

Rejection Under 35 USC 112, First Paragraph

Claims 6, 8 to 10, 12 and 16 were rejected under 35 USC 112, first paragraph, for alleged lack of enablement for the reasons set forth on pages 3 to 8 of the Office Action.

The position was taken in the Office Action that the specification is enabling for treating uveitis, cytomegalovirus retinitis, diabetic retinopathy, proliferative vitreoretinopathy, and retinal detachment, but does not provide enablement for the treatment of age-related macular degeneration, retinitis pigmentosa, central retinal vein occlusion, or central retinal artery occlusion. Further, the position was taken in the Office Action that the specification does not provide enablement for the prevention of uveitis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, retinitis pigmentosa, central retinal vein occlusion, and central retinal artery occlusion.

The claims were amended hereinabove to delete the terminology of "preventing" and to recite only the diseases of the posterior segment that the Examiner indicated were enabled, namely uveitis, cytomegalovirus retinitis, diabetic retinopathy, proliferative vitreoretinopathy, and retinal detachment, as well as age-related macular degeneration.

It is respectfully submitted that the terminology of age-related macular degeneration is enabled for the following reasons.

It has been reported that an intravitreal injection of triamcinolone (a drug disclosed in the present specification as a therapeutic agent) improves visual acuity and fundus findings in exudative macular degeneration (see the enclosed copy of Retina, 20(3), 244-250 (2000)). It has also been reported that an intravitreal injection of triamcinolone may be an acceptable treatment for subfoveal recurrent neovascularisation after laser photocoagulation for exudative macular degeneration (see the enclosed copy of Br. J. Ophthalmol., 86(5), 527-529 (2002)). It is respectfully submitted that in view of the foregoing facts and having the benefit of the disclosure in applicants' specification, the treatment of age-related macular degeneration according to applicants' present claims is enabled.

Withdrawal of the 35 USC 112, first paragraph rejection is thus respectfully requested.

Anticipation Rejections Under 35 USC 102

Claims 1, 6 and 7 were rejected as being anticipated by Gwon et al. (USP 5,300,114) for the reasons stated on pages 8 to 9 of the Office Action.

In view of the above cancellation of claims 1, 6 and 7, withdrawn of this rejection is respectfully requested.

Claims 1, 2, 4, 6 to 8, 10, 12, 14, 16 and 17 were rejected under 35 USC 102 as being anticipated by Peyman (USP 6,395,294) for the reasons indicated on pages 9 to 14 of the Office Action.

It is noted that claims 3 and 9 were not included in this rejection.

Peyman discloses merely a surgical method to alleviate a structural disorder of an eye. Peyman's method requires not only injecting a drug into the eye, but also surgically correcting the disorder by removing the vitreous (see claim 1 of Peyman). In contrast thereto, the presently claimed invention relates to a method of treating an ocular disorder by carrying out only a subconjunctival administration of an injection solution

comprising fine particles containing a drug (see applicants' present claim 8).

Obviousness Rejection Under 35 USC 103

Claims 3, 9 and 13 were rejected under 35 USC 103 as being unpatentable (obvious) over Peyman (USP 6,395,294) in view of Ogura et al. (JP 2000-247871) for the reasons set forth on pages 10 to 11 of the Office Action.

Claim 3 was canceled hereinabove.

Peyman was discussed hereinabove.

It was pointed out in the Office Action that Peyman discloses a particle size of less than 50 μm, and Ogura et al. teach a drug release control system for treating various diseases of a retina or vitreous body, wherein the drug has a particle diameter in the range of 50 to 200 nm. Therefore, it was concluded in the Office Action that it would have been obvious to one of ordinary skill in the art to modify the particle size of the drug, as desired, in order to provide a controlled release of

the drug in the retina (drug emission control over a long period of time).

However, although Peyman discloses that the preferable size of vitreous delineating agents (e.g., corticosteroid) in his surgical method is less than 50 μm, Peyman does not disclose or suggest which particle size is preferable to enable the drug concentration in a retina-choroid to be sustained by a subconjunctival administration of an injection comprising fine particles containing a drug, as recited in applicants' claim 8. Therefore, it is respectfully submitted that Peyman would not lead one of ordinary skill in the art to adjust the particle size of a drug to 50 nm to 150 μm, and such person of ordinary skill in the art would not arrive at the presently claimed invention.

Ogura et al. disclose that the particle diameter must be 50 to 200 nm in order to provide a controlled release of a drug in the retina. In other words, Ogura et al. teach that the drug-containing fine particles whose diameter is more than 200 nm are unfavorable to provide a controlled release of the drug in the retina. In contrast thereto, the particle diameter of the fine

particles in the presently claimed invention is 50 nm to 150 μm, and preferably 200 nm to 75 μm (see page 5, lines 17 to 23 of the present specification). This means that in the presently claimed invention most of fine particles containing a drug have a particle size of more than 200 nm. Accordingly, Ogura et al. thus teach away from the presently claimed invention.

Thus, in Peyman and Ogura et al., there is no teaching or suggestion as to how to arrive at a drug concentration in a retina-choroid to be sustained by a subconjunctival administration, as recited in applicants' present claims.

The present inventors discovered after intensive study that the subconjunctival administration of fine particles containing a drug and enabling the drug concentration in the retina-choroid to be sustained is advantageous for treating a disease of a posterior segment of an eye. It is respectfully submitted that these findings constitute a showing of unexpected results. Moreover, the present invention is also clinically significant since the presently claimed invention reduces the burden of patients by avoiding a vitreous injection and frequent subconjunctival injections.

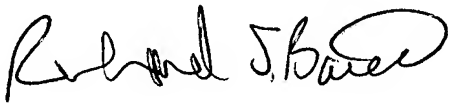
Accordingly, it is respectfully submitted that it would not be obvious for one of ordinary skill in the art to modify the particle size of the drug, as desired, in order to provide a controlled release of a drug in the retina.

Withdrawal of the 35 USC 103 rejection is therefore respectfully requested.

Reconsideration is requested. Allowance is solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



RICHARD S. BARTH
REG. NO. 28,180

FRISHAUF, HOLTZ, GOODMAN & CHICK, P.C.
220 FIFTH AVENUE, 16th FLOOR
NEW YORK, NEW YORK 10001-7708
Tel. Nos. (212) 319-4900
(212) 319-4551/Ext. 219
Fax No. (212) 319-5101
E-Mail Address: BARTH@FHGC-LAW.COM
RSB/ddf
Encs.: (1) a copy of Retina, 20(3), 244-250 (2000)
(2) a copy of Br. J. Ophthalmol., 86(5), 527-529 (2002)